

JOPLIN NEUROSURGICAL ASSOCIATES, INC.

Practice Limited to Neurosurgery
WINDCREST PLAZA - SUITE 7
2902-B McCLELLAND BOULEVARD
P.O. BOX 2602
JOPLIN, MISSOURI 64803
417-781-4733 -- 781-4734
FAX: 417-781-8078

HISH S. MAJZOUB, M.D.

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

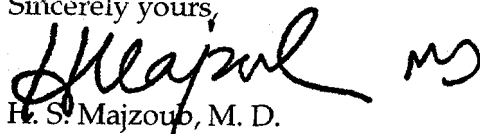
RE: Docket No. 97N-484S

Dear Sir/Madam:

I would like to voice my objection for the proposed FDA regulation that would regulate allografts as medical devices. It would be extremely hard for us, the surgeons, who utilize allografts to treat patients with spine fractures and spine injuries and also degenerative cervical spine disease if we have to use allografts should they become regulated as medical devices. Such a move would definitely hinder the treatment of patients and also make it very hard to obtain the desire allografts to treat patients with such diseases. We feel that such a proposal is ill advised and not necessary as the allograft should be treated as bone tissue and should not be regulated as medical devices.

The proposed regular would impose significant hardship on the surgeon and patient and we feel that this move is not in the best interest of the medical community and also the patients in general.

Sincerely yours,


H. S. Majzoub, M. D.

HSM/cm

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97N-484S

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